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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,231	01/16/2002	William H. Hildebrand	6680.036	8620

30589 7590 06/30/2004

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,231	HILDEBRAND ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1205/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 10/022,066, which claims the benefit of the filing date of provisional application 60/261,978.

Claims 1-31 were originally pending and subject to restriction.

Claims 18-30 have been canceled.

Claims 1-17 and 31 are currently pending and are the subject of examination in the present Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-9, 12-17 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Celia et al. (Proc. Nat. Acad. Sci. (USA) [1999] 96:5634-5639; AT on form PTO-1449).

Celia teaches complexes comprising recombinant soluble MHC class I molecule-peptide complexes captured on the surface of liposomes in an orientation that allows them to bind to a T cell receptor on a T cell (Abstract in particular). Celia teaches that the MHC-peptide complexes are tagged with a histidine tail that allows the complex to bind chemically modified lipids, anchoring the complex to the liposome (Abstract, paragraph bridging pages5635-5636 and Scheme 1 in particular). Celia further teaches that, because the MHC:peptide complexes are properly oriented, the artisan would expect that the liposome complexes would be capable of stimulating T cells. Claims 4-7 and 12-17 are included in this ground of rejection because the product is perceived to be the same, irrespective of the manner in which it is made. The prior art teaching anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-9, 12-17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Celia et al. (Proc. Nat. Acad. Sci. (USA) [1999] 96:5634-5639; AT on form PTO-1449) in view of Albani (WO 00/23053; D on form PTO-1449).

Celia has been discussed supra. Celia does not teach additional signal molecules on the liposomes for manipulating intensity and quality of the T cell response.

Albani teaches complexes comprising a liposome and at least one MHC-peptide complex that is tagged with cholera toxin that anchors the MHC-peptide complex via interaction with GM-1 protein in the bilayer of the liposome (Figures 1-7B; page 12, lines 11-24 and page 21, lines 15-18 in particular) [claims 1, 2, 4-7, 12-17, 31]. Albani further teaches the inclusion of signal molecules in the liposome membrane to manipulate the intensity and quality of the T cell response (page 19, lines 26-27 in particular). Albani further teaches that the liposome-based complexes were capable of interacting with T cells (Figures 16A-18D in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to use the make a liposome complex comprising an MHC-peptide complex for modulating T cell activity because Celia teaches the making of liposomes comprising MHC:peptide complexes in the correct orientation on their surface and Albani teaches that liposomes with MHC:peptide complexes properly oriented on their surface can effectively interact with specific T cells. one would have been motivated to use the histidine tail construct of Celia versus the cholera toxin construct of Albani with a reasonable expectation of success by the fact that the Celia construct does not involve a toxin in its manufacture.

Claims 4-7 and 12-17 are drafted in a product-by-process manner, drawn to the liposome/MHC/ peptide complex, but drafted in a manner reciting the manner of producing the complex. Claims 4-7 and 12-17 are included in this ground of rejection because the product is perceived to be the same, irrespective of the manner in which it is made absent a showing that the method of manufacture necessarily results in a product materially different from the prior art product.

3. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Celia et al. (Proc. Nat. Acad. Sci. (USA) [1999] 96:5634-5639; AT on form PTO-1449) in view of Albani (WO 00/23053; D on form PTO-1449) as applied to claim 7 above, and further in view of Plant et al (Anal. Biochem. [1989] 176(2):420-426; U on form PTO-892) and Walter et al (J. Immunol. Meth. [1998] 214(1-2):41-50; V on form PTO-892).

Celia and Albani have been discussed supra. The combined references do not teach biotinylation of the MHC molecule for attachment to the liposome.

Plant teaches that biotinylation moieties can be incorporated intoi the membrane of liposomes and can bind to avidin-crosslinked molecules (see entire reference, (Abstract in particular). Plant does not teach the biotinylation of soluble MHC molecules,

Walter teaches the biotinylation of soluble MHC molecules that can be attached to avidin moieties for multimerization. Walter further teaches that the avidin-crosslinked MHC molecules were capable of interacting with T cells in an antigen specific manner (see entire reference, (Abstract in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to biotinylate MHC molecules as taught by Walter and linking them to liposomes via avidin crosslinking as taught by Plant as a substitute for the histidine tail/nickel system of Celia. One would have been motivated, with a reasonable expectation of success, to make the change by the knowledge in the art that the biotin avidin system is reliable and safe for in vivo use of therapeutic reagents.

Conclusion

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 21, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
6/28/04